Amendments to the Drawings

The attached sheets of drawings include changes to FIG. 3 and FIG. 5. These sheets replace the original sheets.

In FIG. 3, the sluice mechanism 15 is shown in which the passage for one coronary catheter C is sealed fluid-tight with a coronary catheter C inserted. As discussed at the interview, FIG. 3 is amended to also show that the sluice mechanism seals a passage for the other coronary catheter when the catheter is not inserted (as illustrated by broken lines).

The specification is amended accordingly to recite that Fig. 3 shows (1) a passage pressed apart in a fluid tight matter for one coronary catheter C and other passages I, O, A1, A2, and (2) a passage that is sealed fluid-tight without the provision of a second coronary catheter C.

In FIG. 5, the arrows for both coronary catheters C, both sluice elements 11, and both dilation elements 11' are clarified.

Attachments:

Replacement Sheet for FIG. 3

Replacement Sheet for FIG. 5

REMARKS

Claims 1-3 and 5-15 are pending herein. By this Amendment, Claim 4 is canceled without prejudice or disclaimer, and the specification and Claims 1, 3, 5, and 14 are amended.

Support for the claim amendments is found in the specification at, *inter alia*, page 15, first full paragraph - page 16, second full paragraph; and in the drawings (for example, passages A1, A2, I, O, and C, which are outside of perfusion catheter 1 as shown in FIG. 3 and FIG. 4). No new matter is added by this Amendment.

Applicant thanks Examiner Mehta and Supervisory Examiner Simmons for the courtesies extended to his representative during the January 11, 2007 personal interview. Applicant's summary of the interview is set forth in the foregoing amendments and the following remarks.

I. FINALITY OF OFFICE ACTION

Entry of the Amendment After Final Rejection is proper because it places the application in condition for allowance. Further, at the personal interview, the assertion that FIG. 18 of St. Goar et al. reads on the claims was made for the first time. Prior to the interview, both Office Actions rejected the claims based solely upon FIGS. 8-10 of St. Goar et al., without any discussion of FIG. 18. Thus, Applicant has not previously had an opportunity to respond to this new ground of rejection.

II. FORMAL MATTERS

A. FIG. 3

The Examiner asserted that a sluice mechanism sealing at least one passage fluid tight without the provision of an auxiliary catheter when the dilation unit disposed on the proximal side is in an inflated state must be shown. In a November 29, 2006 telephone conference with Examiner Mehta, the Examiner

asserted that FIG. 3 shows a fluid-tight sluice mechanism for passages with auxiliary catheters C.

As discussed at the interview, FIG. 3 is amended to show the sluice mechanism 15 for a passage in which one of the coronary catheters is not inserted (as illustrated by broken lines). The Examiners agreed that this amendment to the drawings would show that the sluice mechanism seals at least one passage fluid-tight without the provision of an auxiliary catheter. Accordingly, FIG. 3 satisfies the requirements of 37 CFR 1.83(a). Reconsideration and withdrawal of the objection are respectfully requested.

B. FIG. 5

The Examiner asserted that the coronary cuffs shown in FIG. 5 are located on single lines, but that the coronary catheters C are tubular. The Examiner also asserted that the relationship between the catheters C, sluice elements 11, and dilation elements 11' are unclear.

At the interview, the relationship between the catheters C, sluice elements 11 and dilation elements 11' was discussed. The function of sluice elements 11 and dilation elements 11' is clearly disclosed in the specification at, for example, page 17, first full paragraph. As discussed at the interview, FIG. 5 is amended to clarify sluice elements 11 and dilation units 11' by showing arrows to both sluice elements 11 and both dilation elements 11'.

Applicant notes that coronary catheters C are shown schematically as single lines. Schematic drawings are proper. Thus, there is no requirement that the coronary catheters must be depicted as tubes. Further, as disclosed in the specification, one coronary catheter is connected to the left coronary artery and the other coronary catheter is connected to the right coronary artery to supply the coronaries with blood (specification at page 16, last paragraph). The coronary cuffs C' are dilatable balloons by means of which the coronary catheters form a fluid tight occlusion with the inlet opening of the left and right coronary arteries,

respectively (specification at page 9, first full paragraph). FIG. 5 is amended to clarify the arrows to both coronary catheters C.

FIG. 5 would be reasonably ascertainable to one of ordinary skill in the art and satisfies the requirements of 37 CFR 1.83(a). Reconsideration and withdrawal of the objection are respectfully requested.

C. Specification and Claim 5

The specification was objected to as failing to provide antecedent basis for a sluice mechanism sealing at least one passage fluid-tight without the provisional of an auxiliary catheter when the dilation unit disposed on the proximal side is in an inflated state. However, the specification at page 16, lines 10-18 clearly supports this subject matter.

Claim 5 is amended to clarify that the at least one passage is disposed in a rotatable manner about the perfusion catheter with the aid of a rotatable ring seal. The specification provides support for this claim amendment at, *inter alia*, page 15, first full paragraph.

Accordingly, the scope of the specification and Claim 5 would be reasonably ascertainable to one of ordinary skill in the art, thereby satisfying the requirements of 35 U.S.C. 112. Reconsideration and withdrawal of the objection and rejection are respectfully requested.

II. REJECTION UNDER 35 U.S.C. 102(b)

Claims 1-4, 7, and 9-11 were rejected under 35 U.S.C. 102(b) as anticipated by St. Goar et al. (U.S. Patent No. 6,090,096). This rejection is respectfully traversed.

St. Goar et al. discloses a catheter configured to extend into the ascending aorta with a proximal portion of the shaft extending into a left chamber of the heart through the aortic valve and out of the heart through a penetration in a wall thereof (Abstract).

A. FIGS. 8-10

In the embodiment of the catheter shown in FIGS 8-10, the catheter comprises a flexible shaft 82; lumens 86, 92, 98 extending from respective ports inside the shaft through ventricular balloon 110 to openings 90, 96, and 102 respectively (col. 11, lines 4-18). The Examiner interprets passage 98 as a "perfusion channel" so that passage 86 is outside of the perfusion channel. Oxygenated blood is returned to the arterial system via third lumen 98 (col. 11, lines 45-47). Cardioplegic fluid is delivered through first lumen 86 into the aorta (col. 11, lines 50-52).

As discussed at the interview, independent Claim 1 is amended to recite that the at least a dilation unit disposed on the proximal side is provided with at least one passage outside of the perfusion catheter through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner. Thus, as shown in the FIGS., the at least one passage (A1, A2, I, O, C) is outside of perfusion catheter 1.

B. FIG. 18

At the interview, the Examiner questioned whether reference number 224 of FIG. 18 might not read on the claims, particularly regarding coronary catheters C.

As shown in FIG. 18, an arterial return cannula 222 is slidably positioned through a first port 214 and sheath 212 and has a distal end 224 which may be advanced into the ascending aorta (col. 14, lines 46-50). The balloon 232 is inflated and the distal end 224 of arterial return cannula 222 extends distally of balloon 232.

Claim 4 is canceled and its subject matter is incorporated into Independent Claim 1. Thus, Claim 1 recites that the at least one passage projects through said dilation unit and is completely surrounded by said dilation unit. As shown in FIG. 18, arterial return cannula 222 does not project through

balloon 232. Further, arterial cannula 222 is not completely surrounded by balloon 232, but is also in contact with the ascending aorta AA. St. Goar does not disclose passages (e.g., A1, A2, I, and O) that project through dilation unit 2 and are completely surrounded by the dilation unit. See FIGS. 3-4.

St. Goar et al. does not disclose each and every limitation of the claimed device and therefore does not anticipate the claimed device. Reconsideration and withdrawal of the rejection are respectfully requested.

III. REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 5-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. in view of Valley et al. (U.S. Patent No. 5,814,016). This rejection is respectfully traversed.

Valley et al. does not overcome the deficiencies of St. Goar et al. Valley et al. discloses devices and methods for temporarily inducing cardioplegic arrest in the heart of a patient and for establishing cardiopulmonary bypass to facilitate procedures on the heart and its related blood vessels (Abstract).

Like St. Goar et al., Valley et al. does not teach or suggest that a dilation unit disposed on the proximal side is provided with at least one passage (1) outside of the perfusion catheter and (2) that projects through the dilation unit and is completely surrounded by the dilation unit. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al. and Valley et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. in view of Kong (U.S. Patent Application Publication 2002/0120234). This rejection is respectfully traversed.

Kong does not overcome the deficiencies of St. Goar et al. Kong discloses a device, system and method for occluding a body lumen such as a blood vessel having an inner wall (Abstract). Like St. Goar et al., Kong does not teach or suggest that a dilation unit disposed on the proximal side is provided

with at least one passage (1) outside of the perfusion catheter and (2) that projects through the dilation unit and is completely surrounded by the dilation unit. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al. and Kong. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Goar et al. and Kong in view of Wang et al. (U.S. Patent No. 5,195,969). This rejection is respectfully traversed.

Wang et al. does not overcome the deficiencies of St. Goar et al. and Kong. Wang discloses a medical balloon, a catheter utilizing the balloon, and a mechanism to attach the balloon to the catheter tube (Abstract). Wang et al. does not teach or suggest that a dilation unit disposed on the proximal side is provided with at least one passage (1) outside of the perfusion catheter and (2) that projects through the dilation unit and is completely surrounded by the dilation unit. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices in view of the combined teachings of St. Goar et al., Kong, and Wang et al. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 8 and 14-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. in view of Boyd et al. (U.S. Patent No. 5,738,652). This rejection is respectfully traversed.

A. Claim 8

As noted, St. Goar et al. does not teach or suggest that a dilation unit disposed on the proximal side is provided with at least one passage outside of the perfusion catheter that projects through the dilation unit and is completely surrounded by the dilation unit and through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner, as recited in independent Claim 1 and its dependent claims.

Boyd et al. does not overcome the deficiencies of St. Goar et al. Boyd et al. discloses a retrograde delivery catheter which includes at its distal end a balloon configured to occlude the coronary sinus of a patient's heart (Abstract). Like St. Goar et al., Boyd et al. does not teach or suggest that a dilation unit disposed on the proximal side is provided with at least one passage (1) outside of the perfusion catheter and (2) that projects through the dilation unit and is completely surrounded by the dilation unit, as recited in independent Claim 1 and its dependent claims.

B. Claims 14-15

Further, St. Goar et al. does not teach or suggest (1) emptying the blood volume inside two dilation units by introducing at least one auxiliary catheter outside of the perfusion catheter and projecting through the dilation unit disposed on the proximal side to create a working volume, and (2) severing the aortic valve inside said working volume by introducing at least one cutting instrument projecting through said dilation unit disposed on the proximal side as recited in independent Claim 14.

Boyd et al. also does not teach or suggest emptying the blood volume inside two dilation units by introducing at least one auxiliary catheter outside of the perfusion catheter and projecting through the dilation unit disposed on the proximal side to create a working volume. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed devices or practice the claimed methods in view of the combined teachings of St. Goar et al. and Boyd et al. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

/Warren A. Zitlau/

Warren A. Zitlau, Esq.
Registration No. 39,085

CAHN & SAMUELS, LLP
2000 P Street, NW – Suite 200
Washington, DC 20036
Telephone: (202) 331-8777
Facsimile: (202) 331-3838

Date: February 14, 2007